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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/586,037	07/13/2006	Jeffrey L. Southard	560252000800	1724

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EXAMINER	
ROMEO, DAVID S	

ART UNIT	PAPER NUMBER
1647	

MAIL DATE	DELIVERY MODE
08/13/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/586,037	SOUTHARD ET AL.	
	Examiner	Art Unit	
	David S. Romeo	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 May 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15 and 17-27* is/are pending in the application.

4a) Of the above claim(s) *4-8,21 and 22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,9-15,17-20 and 23-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-15 and 17-27* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed 05/21/2010 has been entered. Claims 1–15 and 17–27 are pending.

Maintained formal matters, objections, and/or rejections:

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

Applicant's elected without traverse group I, claims 1–16(in part), 17–19 and 20 (in part), and the species intravenously, diuretics and surface active agents in the reply filed on 10/14/2009.

Claims 4–8 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/14/2009.

Claims 21 and 22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/14/2009.

Claims 1–3, 9–15, 17–20 and 23–27 are being examined to the extent that they are directed to or encompass the elected invention and species.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "improves the quality of life" in claim 19 is a relative term which renders the claim indefinite. The term "improves the quality of life" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The metes and bounds are not clearly set forth.

Response to Arguments

Applicants argue that the term "quality of life" is clearly defined in paragraph 0028 of the Specification, and that one of ordinary skill in the art would readily understand what the term "improves the quality of life" means, and ascertain and confirm that quality of life has been improved. Applicants' arguments have been fully considered but they are not persuasive. The metes and bounds of "improves the quality of life" are dependent upon the view of an indeterminate individual. Thus, the metes and bounds are particular to and vary with the perceptions of a given indeterminate individual. The specification does not provide a standard for ascertaining the requisite degree. The metes and bounds are not clearly set forth.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 10–15, 17–20 and 23–27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stevenson (Int J Cardiol. 1992 Dec;37(3):407-14), Anand (J Am Coll Cardiol. 1991 Jan;17(1):208-17), Shekhar (J Cardiol. 1991 Apr 1;67(8):732-6) and Gennari (Cardiovasc Res. 1990 Mar;24(3):239-41).

Response to Arguments

Applicants argue that:

> None of the cited references… teach or suggest a maintenance therapy, much less a maintenance therapy comprising administration of CGRP at a low dose, e.g., at a rate between about 0.8 to 10 ng/min to relieve or attenuate symptoms or delay progression of said heart failure… .
>
> None of the references teach or suggest administering CGRP "at a rate between about 50 and 500 ng/min for a time between 30 minutes and 8 hours per day as needed to provide symptomatic relief, attenuate symptoms, and/or delay progression of the disease state of heart failure" or "a maintenance therapy comprising administration of CGRP at a rate between about 0.8 to 10 ng/min to relieve or attenuate symptoms or delay progression of said heart failure," as recited in amended claim 1.
>
> With respect to independent claim 17, …[n]one of the cited references…teach or suggest administering CGRP "at a rate between about 500 and 600 ng/min for up to 8 hours per day for at least three consecutive days per week as needed to provide symptomatic relief, attenuate symptoms, and/or delay progression of the disease state of heart failure" or an optional maintenance therapy comprising "administration of CGRP at a rate between about 0.8 to 10 ng/min to relieve or attenuate symptoms or delay progression of said heart failure," as recited in amended claim 17.
>
> …none of the cited references…teach or suggest administering CGRP "at a rate between about 0.8 to 10 ng/min," as recited in newly added claim 26. …none of the cited references…teach or suggest a long term maintenance therapy, e.g., administering maintenance therapy "over a period of 3, 6, or 9 months" as recited in newly added claims 23-25 and 27.

Applicants' arguments have been fully considered but they are not persuasive. Stevenson, Anand, Shekhar and Gennari do teach the general conditions of administering CGRP for the treatment of HF. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. The normal desire of artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of conditions is the optimum combination of dosages and lengths of administration of CGRP to HF patients. The examiner considers the limitations in claims 13–15 and 18 obvious because an artisan would be motivated to administer CGRP to whomever is afflicted with HF, wherever whomever is so afflicted, and for such a duration that would achieve treatment.

Claims 1 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stevenson (Int J Cardiol. 1992 Dec;37(3):407-14), Anand (J Am Coll Cardiol. 1991 Jan;17(1):208-17), Shekhar (J Cardiol. 1991 Apr 1;67(8):732-6) and Gennari (Cardiovasc Res. 1990 Mar;24(3):239-41) as applied to claim 1 above, and further in view of Heim (U. S. Patent No. 5126134), Young (U. S. Patent No. 4627839), Strom (U. S. Patent No. 5336489) and Torgerson (U. S. Patent No. 5820589).

Response to Arguments

Applicants argue that

> …none of the primary references… teach or suggest a maintenance therapy, much less a maintenance therapy comprising administration of CGRP at a rate between about 0.8 to 10 ng/min to relieve or attenuate symptoms or delay progression of said heart failure, as required by

> amended claim 1. Even in view of the secondary references…there is no teaching or suggestion of the use of a maintenance therapy comprising administration of CGRP at a low dose, e.g., at a rate between about 0.8 to 10 ng/min.
>
> None of the secondary references provide the suggestion of a low dose administration of CGRP at a rate between about 0.8 to 10 ng/min.

Applicants' arguments have been fully considered but they are not persuasive. Stevenson, Anand, Shekhar and Gennari do teach the general conditions of administering CGRP for the treatment of HF. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. The normal desire of artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of conditions is the optimum combination of dosages and lengths of administration of CGRP to HF patients.

Claims 1 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stevenson (Int J Cardiol. 1992 Dec;37(3):407-14), Anand (J Am Coll Cardiol. 1991 Jan;17(1):208-17), Shekhar (J Cardiol. 1991 Apr 1;67(8):732-6) and Gennari (Cardiovasc Res. 1990 Mar;24(3):239-41) as applied to claim 1 above, and further in view of Chen (U. S. Patent No. 6525102).

Response to Arguments

Applicants argue that:

> …none of the primary references… teach or suggest a maintenance therapy, much less a maintenance therapy comprising administration of CGRP at a rate between about 0.8 to 10 ng/min to relieve or attenuate symptoms or delay progression of said heart failure… . Even in view of

> the secondary reference, Chen, there is no teaching or suggestion of the use of a maintenance therapy comprising administration of CGRP at a low dose, e.g., at a rate between about 0.8 to 10 ng/min.
>
> Chen does not provide the suggestion of a low dose administration of CGRP at a rate between about 0.8 to 10 ng/min.

Applicants' arguments have been fully considered but they are not persuasive. Stevenson, Anand, Shekhar and Gennari do teach the general conditions of administering CGRP for the treatment of HF. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. The normal desire of artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of conditions is the optimum combination of dosages and lengths of administration of CGRP to HF patients.

New Formal Matters, Objections and/or Rejections

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 26 is rejected under 35 U.S.C. 102(b) as being anticipated by Anand (J Am Coll Cardiol. 1991 Jan;17(1):208-17) or Shekhar (J Cardiol. 1991 Apr 1;67(8):732-6).

Anand teaches that CGRP may be useful in some forms of heart failure (Abstract). Anand administered CGRP to patients with congestive HF. All were taking diuretics. See paragraph bridging pages 208-209. The peptide was infused into a forearm vein using an infusion pump. Incremental infusions of CGRP at the dose of 0.8, 3.2 and 16 ng/kg/min were made, the first two doses were infused for 10 min each. The highest dose was infused for 20 min.

Shekhar infused CGRP into a forearm vein of patients with heart failure using an infusion pump at a does of 8.0 ng/kg/min for 8 h (paragraph bridging pages 732-733), or about 500 ng/min, assuming a 70 kg patient. The dose was midway between the low doses (0.8 and 3.2 ng/kg/min) high dose (16 ng/kg/min) used in previous (Anand (1991)) regimens (page 735, left column). Shekhar concludes that in patients with HF, CGRP has sustained beneficial effects; CGRP also increases renal blood flow and glomerular filtration (Abstract). According to Shekhar, all of the patients that received CGRP were taking diuretic drugs (page 732, right column, full paragraph 2).

"ng/min" (claim 26) is generic to ng/kg/min.

Conclusion

No claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (571) 272-0890. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 9:00 A.M. TO 5:30 P.M. IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY NICKOL, CAN BE REACHED AT (571)272-0939.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE CENTRAL FAX NUMBER FOR OFFICIAL CORRESPONDENCE, WHICH IS (571) 273-0835.

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING MAY BE OBTAINED FROM THE PATENT APPLICATION INFORMATION RETRIEVAL (PAIR) SYSTEM. STATUS INFORMATION FOR PUBLISHED APPLICATIONS MAY BE OBTAINED FROM EITHER PRIVATE PAIR OR PUBLIC PAIR. STATUS INFORMATION FOR UNPUBLISHED APPLICATIONS IS AVAILABLE THROUGH PRIVATE PAIR ONLY. FOR MORE INFORMATION ABOUT THE PAIR SYSTEM, SEE HTTP://PAIR-DIRECT.USPTO.GOV. CONTACT THE ELECTRONIC BUSINESS CENTER (EBC) AT 866-217-9197 (TOLL-FREE) FOR QUESTIONS ON ACCESS TO THE PRIVATE PAIR SYSTEM,

/DAVID S ROMEO/
PRIMARY EXAMINER, ART UNIT 1647

DSR
AUGUST 11, 2010